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REMARKS

Claims 46, 75 and 77 are currently amended. Claims 66, 67 and 85 have been cancelled without prejudice or disclaimer. Claims 86 and 87 have been added. Claims 46, 48-65, 68-84 and 86-87 are pending in the application.

It is respectfully submitted that the present amendment presents no new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 46, 50, 51 and 68-71 under 35 U.S.C. 112

Claims 46, 50, 51 and 68-71 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Please consider currently amended claim 46 (and claims which depend thereon) in light of the amendments above and comments below.

A specification complies with the written description requirement if it provides "a precise definition, such as by structure, formula, chemical name, or physical properties of the claimed subject matter sufficient to distinguish it from other materials." See, e.g., *University of California v. Eli Lilly and Co.*, 43 U.S.P.Q.2d 1398, 1404 (Fed. Cir. 1997); *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d 1609, 1613 (Fed. Cir. 2002). The test is not whether one of ordinary skill in the art envisions all of the claimed subject matter, as suggested in the Office Action. Indeed, the Federal Circuit held that, "It is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement." *Enzo Biochem v. Gen-Probe Inc.*, 63 U.S.P.Q.2d at 1613.

Claim 46, as amended, is drawn to a variant of a *Myceliophthora thermophila* laccase including an amino acid sequence at least 98% identical to the amino acid sequence of SEQ ID NO: 10. Although the terms "at least 98% identical" do not appear in the original specification, it is settled case law that the exact words of a claim need not appear in the specification in order for that specification to satisfy the description requirement of Section 112. See *In re Wright*, 9 USPQ 24, 1649, 1651, CAFC, 1989 for a case right on point.

Further, one skilled in the art of molecular biology would clearly recognize that at the time the application was filed the inventors clearly had possession of the claimed invention in that 14 positions out of the 573 amino acids shown on SEQ ID NO:10 could be modified (97.6% identity). To show support for the amendment to claim 46, the following discussion is provided.

First, the specification fully describes the Coprinus-like laccase, *i.e.*, *Myceliophthora thermophila* laccase including the amino acid sequence shown in SEQ ID NO:10. See page 2, line 30, and SEQ ID NO:10 at pages 24-26. Second, the specification specifically recites preferred positions for mutations including the following: MTL: V52, G121, F141, Y177, H206, M260, P336, T365, I380, I382, V406, A506, W507, W543, wherein MTL: *Myceliophthora thermophil* laccase includes the amino acid sequence shown in Seq ID NO:10. See Detailed Description page 6, lines 30-35 to page 7, line 4. One skilled in the art of molecular biology would clearly recognize from this disclosure that 14 positions of the 573 amino acids shown on SEQ ID NO:10 could be modified in accordance with the present disclosure, *i.e.* 97.6% identity. Third, the specification further describes variants of a parent *Myceliophthora thermophil* laccase including mutations in positions corresponding to at least one of 14 positions in SEQ ID NO:10. See page 8, lines 5-20. Again, one skilled in the art of molecular biology would clearly recognize from this disclosure that 14 positions of the 573 amino acids shown on SEQ ID NO:10 could be modified in accordance with the present disclosure, *i.e.* 97.6% identity. Fourth, support can also be found in original claim 2 relating to a variant of a parent *Myceliophthora thermophil* laccase including a mutation in a position corresponding to at least one of 14 positions in SEQ ID NO:10. Specifically the following positions were listed as V52, G121, F141, Y177, H206, M260, P336, T365, I380, I382, V406, A506, W507, and/or W543. By reciting "and/or" one of skill in the art would know from this disclosure that at least one or all of the positions may be modified in accordance with the present disclosure, *i.e.* an amount of 97.6% through and including about 99% identical. Finally, the Examiner has correctly acknowledged in the Official Action that "The specific substitutions represent about 0.17%-1.7% of SEQ ID NO:10 that is 573 amino acid long." Thus, the Examiner, while looking at 10 specifically claimed positions, described embodiments including about 98% identity. Accordingly, it is submitted that the specification fully describes the variants, including claimed 98% identity to amino acid sequence of SEQ ID NO: 10.

Finally, based on Applicants' disclosure, the skilled artisan would be led to make variants in addition to the variants recited in the claims to obtain the benefits described in the present application. Applicants therefore submit that the specification demonstrates that Applicants had possession of the claimed invention at the time the application was filed.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 46, 50, 51 and 68-71 under 35 U.S.C. 112

Claims 46, 50, 51 and 68-71 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement. The Examiner alleges that the claim(s) contain subject matter which was not described in the specification in such a way as to enable one of skill in the art to which it pertains, or with which is most nearly connected, to make and/or use the invention.

Please consider currently amended claim 46 (and claims which depend thereon) and the comments below.

It is well settled that "[t]he first paragraph of section 112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance." *In re Marzocchi*, 169 USPQ 367, 369 (CCPA 1971). Moreover, "a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of section 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 169 USPQ at 369.

"The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art ... The test is not quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed ..." *Ex parte Jackson*, 217 U.S.P.Q. 804 (Bd. Pat. App. 1982).

It is also well settled that an assertion by the Patent Office that the enabling disclosure is not commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubts so expressed. *In re Dinh-Nguyen*, 181 U.S.P.Q. 46 (C.C.P.A. 1974). See also *U.S. v. Telectronics*, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988); *In re Bowen*, 181 U.S.P.Q. 48 (C.C.P.A. 1974); *Ex parte Hitzeman*, 9 U.S.P.Q.2d 1821 (BPAI 1988).

Moreover, in the absence of any evidence or apparent reason why compounds do not possess the disclosed utility, the allegation of utility in the specification must be accepted as correct. *In re Kamal*, 158 U.S.P.Q. 320 (C.C.P.A. 1968). See also *In re Stark*, 172 U.S.P.Q. 402, 406 n. 4 (C.C.P.A. 1972) (the burden is upon the Patent Office to set forth reasonable grounds in support of its contention that a claim reads on inoperable subject matter).

Moreover, the Examiner has relied heavily on the *In Re Wands* factors in concluding that the specification lacks enablement. In *Wands*, the Court **actually** decided "that the specification was enabling with respect to the claims at issue and found the 'there was considerable direction and guidance' in the specification . . ." See MPEP 2164.01(a). It is respectfully submitted that the instant specification also provides considerable direction and guidance in light of the fact that it completely describes the claimed variants. With respect to *Myceliophthora thermophila* laccase, the specification describes, *inter alia*:

- The Coprinus-like laccase, i.e., *Myceliophthora thermophila* laccase including the amino acid sequence shown in SEQ ID NO:10. See page 2, line 30, and SEQ ID NO:10 at pages 24-26.
- Preferred positions for mutations including the following: MtL: V52, G121, F141, Y177, H206, M260, P336, T365, I380, I382, V406, A506, W507, W543, wherein MtL: *Myceliophthora thermophil* laccase compris[es] the amino acid sequence shown in Seq ID NO:10. See Detailed Description p.6, lines 30-35 to page 7, line 4.
- Variants of a parent *Myceliophthora thermophil* laccase including a mutation in a position corresponding to at least one of 14 positions in SEQ ID NO:10. See page 8, lines 5-20.
- A variant of a parent *Myceliophthora thermophil* laccase including a mutation in a position corresponding to at least one of 14 positions in SEQ ID NO:10. Specifically the following positions were listed as V52, G121, F141, Y177, H206, M260, P336, T365, I380, I382, V406, A506, W507, and/or W543. See original claim 2.

Accordingly, variant embodiments are completely described. Moreover, the specification includes methods of preparing laccase variants as well as testing of variants of the present disclosure. See Page 12, line 22 through and including page 20. "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement . . . is satisfied." *In re Fisher*, 427 F.2d. 833, 839 (CCPA 1970). See also MPEP 2164.01(b). One of ordinary skill in the art would clearly understand the meaning of the claimed variants.

For the foregoing reasons, Applicants submit that the claims overcome this rejection under 35 U.S.C. 112. Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 75 and 77 under 35 U.S.C. 112, Second Paragraph

Claims 75 and 77 are currently amended. It is respectfully submitted that these claims are clear. Reconsideration is urged.

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III. The Rejection of Claims 46 and 75 under 35 U.S.C. 102


Claims 46 and 75 are currently amended. Reconsideration is urged.

IV. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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Michael W. Krenicky, Reg. No. 45,411
Novozymes North America, Inc.
500 Fifth Avenue, Suite 1600
New York, NY 10110
(212) 840-0097